NOV 2 2 2011 K112784

1 of 3

510(k) Summary

General Information

Submitters Name/Address:	Smith & Nephew, Inc. 970 Lake Carillon Drive Suite 110 St. Petersburg, FL 33716
Establishment Registration Number:	3006760724
Contact Person:	Laura D. Reynolds Director, Regulatory Affairs
Phone Number:	(727) 329-7702
Date Prepared:	November 1, 2011
Trade Name:	RENASYS™ AB Abdominal Dressing Kit with Soft Port
Generic/Common Name:	NPWT Abdominal Wound Dressing Kit
Classification Name:	Mesh, Surgical, Polymeric, 21 CFR 878.3300
Product Classification/Code:	Class II, FTL

Predicate Device Information

510(k) #	Device	Manufacturer	Clearance Date
K100787	RENASYS™ F/AB Abdominal Dressing Kit	Smith & Nephew, Inc.	9/17/2010
K110647	RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port	Smith & Nephew, Inc.	6/22/2011

Device Description

The RENASYS™ AB Abdominal Dressing Kit with Soft Port consists of two large hydrophobic reticulated polyurethane foam dressings that incorporate several cuts to facilitate custom sizing if needed. Also included in the kit are a polyurethane organ protection layer, six transparent film drapes and a Soft Port suction port assembly with tubing that attaches to the exudate canister. The kit is designed specifically for abdominal wounds and is supplied sterile, single use.

The modification to this kit is the inclusion of a Soft Port suction port, to replace the existing suction port.

The RENASYS AB Abdominal Dressing Kit is used in conjunction with Smith & Nephew RENASYS EZ and RENSASYS EZ PLUS negative pressure wound therapy pumps and canister kits, which have been cleared under 510(k) numbers K082426 and K091470.

Indications for Use

The RENASYS AB Abdominal Dressing Kit with Soft Port is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.

The RENASYS AB Abdominal Dressing Kit with Soft Port is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

Non-Clinical Tests (Bench)

Design verification testing has been conducted to verify the Soft Port suction device meets the required specifications and functions equivalent to the existing suction port component in the kit. Testing verified that the Soft Port meets the design specifications and demonstrated substantial equivalence to the predicate device.

Summary of testing conducted:

- Laboratory testing was completed to confirm the Soft Port and the existing suction port demonstrate comparable performance patterns when tested with clottable blood.
- Testing to verify that the Soft Port performs to specification when it is placed under excessive weight, becomes blocked by compression, folding, or is subjected to particulate challenge.
- Testing to verify the Soft Port assembly will effectively remove exudate from the abdomen at the predetermined flow rate for a minimum of 48 hours.
- Testing to verify that the new "quick-click" connector establishes a secure connection to the exudate canister tubing.

The following biocompatibility testing for all kit components has been successfully completed per applicable parts of ISO 10993:

Kit Component	Tests Completed
Foam	Cytotoxicity Irritation Sensitization
Organ Protection Layer	Cytotoxicity Irritation Sensitization Implantation Sub-acute Toxicity Genotoxicity
Transparent Film Drape	Cytotoxicity Irritation Sensitization
Soft Port Suction Assembly	Genotoxicity Cytotoxicity Irritation Sensitization Sub-acute Toxicity

Conclusion

In establishing substantial equivalence to the currently marketed devices, Smith & Nephew, Inc evaluated the indications for use, materials, technology and product specifications of the device. Performance testing has been successfully completed to demonstrate that the RENASYS AB Abdominal Dressing Kit with Soft Port is substantially equivalent to the marketed device and is appropriate for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 22 2011

Smith & Nephew, Inc.
% Ms. Laura D. Reynolds
Director, Regulatory Affairs
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

Re: K112784
Trade/Device Name: RENASYS™ AB Abdominal Kit with Soft Port
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: November 01, 2011
Received: November 02, 2011

Dear Ms. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112784

Device Name: RENASYS™ AB Abdominal Kit with Soft Port

Indications for Use:

The RENASYS AB Abdominal Kit with Soft Port is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.

The RENASYS AB Abdominal Kit with Soft Port is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112784